UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,023	08/06/2001	Tor Regberg	PU-9843	6811

22840 7590 05/05/2006

GE HEALTHCARE BIO-SCIENCES CORP.
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/869,023
Filing Date: August 06, 2001
Appellant(s): REGBERG ET AL.

MAILED
MAY 05 2006
GROUP 1600

Royal N. Ronning, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the remand filed 3/31/06 from the examiner's answer mailed 10/22/04.

NEW GROUND(S) OF REJECTION

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-8 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) New Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, subsection (b) recites "R_{1-4} are selected from hydrogen, electron withdrawing groups such as halogens and lower alkyl groups (C_{1-10}) that possibly are substituted with electron withdrawing groups, such as halogens;". This is vague and indefinite as to the metes and bounds of the envisioned invention because it is not clear if the electron withdrawing groups are required limitations of the claims. It is conventional in the art to refer to such substituents as optional. Further, the metes and bounds of the electron withdrawing groups is unknown, since the claims recite "such a halogens" and the specification provides no further guidance on the selection of suitable electron withdrawing groups.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue

experimentation (MPEP 2164.01(a)). The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The claimed invention is drawn to a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand (=X). The ligand having affinity for and enabling binding of the serum albumin.

The instant specification discloses that 14 ligand structures, (pages 13-14), and 3 proteins, (page 14, lines 2-4) were tested for binding interaction. At page 16, lines 2-4, it is disclosed that based on conventional ways of interpreting the chromatogram recorded of the binding to a solid support comprising the ligands, , none of the ligand structures showed binding to IgG or HSA .Further, the instant specification recites that all chromatograms for IgG looked the same and the position of the eluted IgG suggested no interaction/binding (see page 16, lines 9-11). However, the specification further states that the inventors went further on and analyzed in more detail the shape and position of the peaks in the chromatogram (see page 16, lines 6-7). Ligands 1, 2, 5, 7, 10, 11,and 14 are said to show "retardation of the peaks", "two peaks in the flow through", "peaks with a shoulder", or "retarded peaks that were tailed" (see page 16,

paragraph 2), but provided no actual data for consideration, merely these conclusory remarks. The specification provides no guidance as to what further steps were necessary to visualize the aforementioned details.

The specification provides no specific working examples of the claimed method of removing serum albumin from a mixture of other compounds using a ligand within the scope of the claims. At best, the specification only provides that ligand 11is able to weakly bind to HSA (which is not a mixture with other compounds) under specific binding and elution conditions (paragraph bridging pages 16-17), but does not demonstrate how this weak binding can be used in the claimed method of separating or enriching albumin from a complex mixture for this ligand let alone for ligands within the scope of the claims. That is, the specification does not disclose how to visualize the binding of a ligand to a mammalian serum albumin or how to use such binding to selectively remove or enrich albumin from a complex mixture. One skilled in the art would not have been able to determine whether any particular ligand selectively enriched or removed any serum albumin from a mixture of other compounds without undue experimentation.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

(11) Response to Argument

Appellant points to experimental results on pages 16-17 of the instant specification. Specifically, as stated on page 16, structures 1-14 were tested for binding HSA in PBS at pH 7 and 7 structures (# 3, 4, 6, 8, 9, 12, and 13) showed an HSA peak located at the same elution volume and having the same shape. The other structures (# 1, 2, 5, 7, 10, 11, and 14) allegedly had an interaction with the media as evidenced from the shoulders and tailing of the peaks (not shown). Appellants assert this demonstrates that such compositions are useful for enriching/ removing a serum albumin from a mixture of other compounds, and further, that such analyses of the chromatograms are known and practiced by those skilled in the art. However, the examiner contends that the appellant's instant specification did something not conventional in the art (see page 16, line 6). Appellant's brief states such analyses of the chromatograms are known and practiced by those skilled in the art, however, the instant specification states that based on conventional ways of interpreting the chromatogram recorded, none of the ligand structures showed binding to IgG or HSA. No adequate guidance is provided or explanation given, nor does the brief contain evidence to support how to use the invention because interaction is so weak the claimed method of separating or enriching albumin from a complex mixture cannot be practiced by one of ordinary skill in the art without undue experimentation.
For the above reasons, it is believed that the rejection should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(10)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer

exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Roy Teller

4/27/06

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Bruce Kisliuk

Conferees:

Bruce Campell

Jon Weber

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JON WEBER
SUPERVISORY PATENT EXAMINER

Bruce M. Kisliuk, Director
Technology Center 1600

Royal N. Ronning, Jr.

Amersham Biosciences Corp.

800 Centennial Avenue

P.O. Box 1327

Piscataway, New Jersey 08855-1327